11-03-00 A

Attorney's Docket No. **760-35**

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of

Inventor(s): **GIRTON, Timothy Samuel,** a U.S. citizen, whose address is
15082 75th Avenue N.
Maple Grove, MN 55311

For (title): **STENT COVERING FORMED OF POROUS POLYTETRAFLUOROETHYLENE**

CERTIFICATION UNDER 37 CFR 1.10

I hereby certify that this New Application Transmittal and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date, **November 2, 2000**, in an envelope as "Express Mail to Addressee" Mailing Label Number **EF110947091US**, addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Kathleen J. Goodhand
Name of person mailing paper

Kathleen J. Goodhand
Signature of person mailing paper

1. Type of Application

This new application is a(n):

[X] Original (nonprovisional) application.

[ ] Design application.

[ ] Plant application.

[ ] Divisional of Serial No. _____, filed on_____, under

[ ] 37 CFR 1.53 [ ] 37 CFR 1.60

[ ] Continuation of Serial No. 08/_____, filed on _____, under

[ ] 37 CFR 1.53 [ ] 37 CFR 1.60.

[ ] Continuation-in-part of Serial No. 08/_____, filed on _____, under

[ ] 37 CFR 1.53 [ ] 37 CFR 1.62.

2. Benefit of Prior U.S. Application(s) (35 U.S.C. 119(e), 120, or 121)

[ ] This new application claims the benefit of prior U.S. application(s).

[ ] Please amend the specification by inserting, before the first line, the following:

[ ] "This application claims the benefit of U.S. Provisional Application No. _/_____, filed on _____."

[ ] "This application is a
[ ] continuation
[ ] continuation-in-part
[ ] divisional
of copending application
[ ] Serial No. _____, filed on_____."
[ ] International Application No._____, filed on _____, and which designated the U.S."

[ ] A Preliminary Amendment is enclosed amending this application to state the relation of this application to prior applications.

[ ] The relation of this application to prior applications is stated in the application.

3. **35 U.S.C. 119 Priority Claim for Prior Application**

This application, and prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 2, claim(s) priority from one or more foreign applications as follows:

(Country)	(Application No.)	(Filing Date)
(Country)	(Application No.)	(Filing Date)
(Country)	(Application No.)	(Filing Date)

Certified copy(ies) of the application(s) from which priority is claimed:

[ ] has(have) been filed on _____, in prior application 08/_____, which was filed on _____.
[ ] is (are) enclosed.
[ ] will follow.

4. **Papers Enclosed Which are Required to Obtain Application Filing Date under 37 CFR 1.53(b) (Regular) or 37 CFR 1.153 (Design)**

9 Pages of specification
3 Pages of claims
1 Pages of Abstract
7 Sheets of drawings
[ ] formal
[X] informal

[ ] The enclosed drawing(s) include photograph(s), and there is also attached a "Petition to Accept Photograph(s) as Drawings." 37 CFR 1.84(b).

5. **Additional Papers Enclosed**

[ ] Preliminary Amendment

[ ] Information Disclosure Statement (37 CFR 1.98)

[ ] Form PTO-1449

[ ] Citations

[ ] Declaration of Biological Deposit

[ ] Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence

[ ] Authorization of Attorney(s) to Accept and Follow Instructions from Representative

[ ] Special Comments

[ ] Power of Attorney

[ ] Other

6. Declaration or Oath

[X] A Declaration or Oath is enclosed, executed by (check all applicable boxes):

[X] inventor(s).

[ ] legal representative(s) of inventors(s) (37 CFR 1.42 or 1.43).

[ ] joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

[ ] This transmittal serves as the petition required under 37 CFR 1.47, and the statement required under 37 CFR 1.47 is also enclosed. See item 13 below for fee.

[ ] A Declaration or Oath was filed on _____ in prior application _____, filed on_____, from which benefit is being claimed for this application under 35 U.S.C. 120 or 121. The subject matter disclosed in the present application is the same as that disclosed in the prior application, and the inventors are the same or less than those named in the prior application. Accordingly, no new Oath or Declaration is required.

[ ] A copy of the Oath or Declaration in the prior application is enclosed.

[ ] A Declaration or Oath is not enclosed.

[ ] Application is made by a person authorized under 37 CFR 1.41(c) on behalf of *all* of the above named inventor(s).

[X] A Power of Attorney is included in the Declaration or Oath.

7. **Language**

This new application is written in:

[X] English.

[ ] A non-English language: _____.

[ ] A verified translation is enclosed (37 CFR 1.52(d)).

8. **Assignment**

[X] An assignment of the invention to **Scimed Life Systems, Inc.**
One Scimed Place; Maple Grove, MN 55311-1566

[X] is enclosed. A separate:

[ ] "Cover Sheet for Assignment (Document) Accompanying New Patent Application" is enclosed.

[X] Form PTO-1595 is enclosed.

[ ] was made in prior application No. _____, filed on _____.

[ ] A copy of the assignment (and any recordation cover sheet) is enclosed.

[ ] will follow.

9. **Maintenance of Copendency of Prior Application**

[ ] A Petition for Extension of Time and the appropriate fee has been filed and extends the term in the pending prior application until _____.

[ ] A copy of the petition filed in the prior application is attached.

[ ] A conditional petition for extension of time is being filed in the pending prior application.

[ ] A copy of the conditional petition in the prior application is attached.

10. **Abandonment of Prior Application**

[ ] Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

11. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

[ ] There is provided herewith a Petition to Suspend Prosecution for the Time Necessary to File an Amendment.

12. Fee Calculation (37 CFR 1.16)

A. [X] Regular application (37 CFR 1.16(a)) Basic Fee $710.00

FEES FOR CLAIMS AS FILED

Number filed		Number extra		Rate		
Total Claims (37 CFR 1.16(c))	**16** - 20 =	**0**	X	$ 18.00	=	**$ 0**
Independent Claims (37 CFR 1.16(b))	**4** - 3 =	**1**	X	$ 78.00	=	**$ 78.00**
Multiple Dependent Claims (37 CFR 1.16(d))			+	$260.00	=	$--------

Fee Calculation for Extra Claims $ **78.00**

[ ] Amendment canceling extra claims enclosed.

[ ] Amendment deleting multiple-dependencies enclosed.

B. [ ] Design application (37 CFR 1.16(f)) Filing Fee $310.00

C. [ ] Plant application (37 CFR 1.16(g)) Filing Fee $480.00

Total Filing Fee Calculation $**788.00**

13. Request for International-Type Search (37 CFR 1.104(d))

[ ] Please prepare an international-type search report for this application at the time national examination on the merits takes place. See item 15 for fee.

14. Small Entity Statement(s)

[ ] A Verified Statement that this is a filing by a small entity under 37 CFR 1.9 and 1.27;

[ ] is enclosed.
[ ] will follow.

[ ] Status as a small entity was claimed in prior application 08/_____, filed on _____, from which benefit is being claimed for this application under:

[ ] 35 U.S.C. 119(e),
[ ] 35 U.S.C. 120,
[ ] 35 U.S.C. 121,
[ ] 35 U.S.C. 365(c),

and which status as a small entity is still proper and desired.

[ ] A copy of the verified statement in the prior application is enclosed.

Filing Fee Calculation (50% of **A**, **B**, or **C** above) $_____

15. Fee Payment Being Made at This Time

[ ] Not enclosed. No filing fee is to be paid at this time.

[X] Enclosed:

[X]	Basic filing fee (Item 12 or 14 above)	$788.00
[X]	Fee for recording Assignment ($40.00 (37 CFR 1.21(h)))	$ 40.00
[ ]	Petition fee for filing by other than all of the inventors or person on behalf of the inventor where inventor refused to sign or cannot be reached. ($130.00 (37 CFR 1.47 and 1.17(h)))	$_____
[ ]	Fee for processing an application having a specification in a non-English language. ($130.00 (37 CFR 1.52(d) and 1.17(k)))	$_____
[ ]	Processing and retention fee ($130.00 (37 CFR 1.53(d) and 1.21(l)))	$_____

[ ] Fee for international-type search report ($40.00 (37 CFR 1.21(e))) $_____

Total fees enclosed $**828.00**.

16. Method of Payment of Fees

[X] Check in the amount of $**828.00**.

[ ] Charge Deposit Account No. 08-2461 in the amount of $_____.
A duplicate of this transmittal is enclosed.

17. Authorization to Charge Additional Fees

[X] The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Deposit Account No. 08-2461:

[X] 37 CFR 1.16(a), (f), or (g) (filing fees)

[X] 37 CFR 1.16(b), (c), and (d) (presentation of extra claims)

[ ] 37 CFR 1.16(e) (surcharge for filing the basic fee and/or declaration at a date later than the filing date of the application)

[ ] 37 CFR 1.17 (application processing fees)

A duplicate of this transmittal is enclosed.

18. Instructions as to Overpayment

[X] Credit Deposit Account 08-2461.

[ ] Refund.

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Attorney for Applicant(s)

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760-35 PATENT

STENT COVERING FORMED OF POROUS POLYTETRAFLOUROETHYLENE

Inventor: Timothy Samuel Girton

760-35 PATENT

STENT COVERING FORMED OF POROUS POLYTETRAFLUOROETHYLENE

FIELD OF THE INVENTION

The present invention relates to an endoprosthesis device or intraluminal device, in particular a stent, having a covering comprising porous polytetrafluoroethylene formed by removing the siloxane from an interpenetrating network of polytetrafluoroethylene and siloxane, and to a method of making the endoprosthesis device. The stent covering can be applied on the exterior surface of the stent, on the interior surface of the stent, or both, at a thickness of as low as about 15 microns.

BACKGROUND OF THE INVENTION

Endoprosthesis devices including stents, stent-grafts, grafts, vena cava filters, balloon catheters, and so forth, are placed or implanted within various body vessels for the treatment of various diseases. One particular type of an endoprosthesis device is the stent. A stent is implanted within a vessel for the treatment of stenoses, strictures, or aneurysms in the blood vessels. The devices are implanted within the vascular system to reinforce diseased, partially occluded, weakened or abnormally dilated sections of the blood vessel. Stents are often employed after angioplasty to prevent restenosis of a diseased blood vessel. While stents are most notably used in blood vessels, they have also been implanted in other bodily vessels including urinary tracts and bile ducts to reinforce and prevent neoplastic growth.

Stents are typically longitudinal tubular devices formed of biocompatible materials and come in a variety of construction types, and are often expandable in nature. Many if not all of the materials used for stents involve metal or carbon fiber materials which are highly electro-positive and are bio-active. Since stents tend to be used under conditions were they are counteracting disease processes, supporting healing processes, or guarding against stenosis of a passage, bio-activity, which may encourage undesirable or poorly regulated growth processes, or lead to clot formation, should be avoided.

Coating of the stent can keep the stent from directly contacting surrounding tissue or fluids, and thus can theoretically protect against unwanted electrochemically induced tissue reactions.

In the field of expandable stents, a further problem arises due to the fact that many stent constructions involve structures that have numerous apertures or spaces between various strands or structural elements of the stent such as those structures that are filamentous, wire-like, or of a tubular nature in which various openings have been cut or etched into the stent. With these constructions, tissue may grow through the openings of the stent. Furthermore, the stent itself may provoke a foreign body reaction and be both a stimulus for and a framework supporting, proliferative tissue growth, resulting, for example, in scar tissue or restenosis of the very region it is placed to control.

One approach to this drawback is to provide a coating, liner, cover or both, for the stent which prevents the healing or diseased layer of tissue from directly contacting the stent, or from passing through the stent in any way. Such liners may be formed, for example, of porous polytetrafluoroethylene (PTFE) which allows the passage of fluids and vital materials while serving as a barrier to tissue growth. However, when applying such a construction, a further difficulty which may arise is that the layer or sleeve of polymer must be attached to the stent for example, by staples or sutures at one end, or is prone to developing loose pockets or folds which might accumulate organic matter or lead to sepsis or unusual growth. Also, the necessarily thin liner material may detach or degrade. The risk of loose or unattached liner material is particularly great for constructions which utilize poorly adherent polymers, such as PTFE, or structures which seek to combine an expandable stent of stiff material, which changes both its dimension and its shape, with a dissimilar liner or shell.

One method for overcoming these problems is found in US 6010529 in which tube of polymeric material, e.g. expanded polytetrafluoroethylene (PTFE), is passed through the interior of a stent body and is turned back upon itself over the stent to form a cuff. The assembly is then

heated and the outer layer contacts and coalesces with the inner layer, closely surrounding the stent body within a folded envelope having a continuous and seamless end. Porosity is imparted to the PTFE by previous stretching or expansion the material.

Another type of covered stent which permits radial expansion is shown in WO 96/00103. As shown and described therein, a metallic expandable stent includes an outer covering of ePTFE. The ePTFE cover exhibits suitable expansion capabilities so as to enable the cover to expand upon expansion of the underlying stent. A polytetrafluoroethylene/lubricant blend may be extruded into a tube and the tube heated to remove the lubricant. Then, in order to impart the expandable characteristics to the ePTFE cover during formation of the ePTFE cover material, the ePTFE must undergo successive processing steps of expanding the material, sintering the material, radially dilating the material and resintering the dilated material, a procedure that is quite process intensive. The device described therefore requires precise manufacturing techniques and is extremely processing sensitive. Careful processing of the material forming the cover is required in order for the cover to exhibit sufficient expansion capabilities.

US 5824046 describes a composite intraluminal device, in particular an elongate radially expandable tubular stent having an interior luminal surface and an opposed exterior surface extending along a longitudinal stent axis. A stent cover is formed of unsintered ePTFE which is expandable.

There remains a need in the art to provide a stent with a cover material that is sufficiently expandable, has the requisite barrier properties and yet allows the passage of fluids and vital materials, without requiring extensive processing procedures and is thus easily manufactured and applied to the stent.

SUMMARY OF THE INVENTION

The present invention relates to a method of forming porous polytetrafluoroethylene (PTFE) without having to stretch or expand the material, and to a radially expandable endoprosthesis device covered with the solid but expandable polymer covering comprising the

porous PTFE material obtained using the method of the present invention. The porous PTFE covering physically isolates the endoprosthesis from surrounding blood and tissue.

Specifically, the porous PTFE is prepared by extracting siloxane from an interpenetrating network (IPN) of PTFE and siloxane, leaving behind a porous PTFE structure without having to expand and stretch the PTFE. Consequently, the PTFE material used in the endoprosthesis device coverings of the present invention is not *expanded* PTFE, but it is porous.

In one embodiment the end of the prosthesis device of the present invention includes an elongate radially expandable tubular stent having an interior surface and in exterior surface extending along a longitudinal stent access. The expandable tubular stent has a stent cover on said interior surface, exterior surface or both, the cover being formed of a porous polytetrafluoroethylene. The porous polytetraflouroethylene cover is a non-stretched porous structure, the non-stretched structure lacking note and viable structure.

In particular, the present invention relates to a radially expandable stent for use in treating stenoses wherein the stent is covered with an expandable polymer covering comprising the porous PTFE prepared according to the present invention that physically isolates the stent from surrounding blood and tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of one type of intraluminal device that may be used in the present invention.

Fig. 2 is a perspective view of a different intraluminal device which may be used in the present invention.

Fig. 3 is a perspective view of the intraluminal device of fig. 1 illustrating the device having a polytetrafluoroethylene cover on both the inner and outer surface of the device.

Fig. 4 is a cross-sectional view of the same intraluminal device shown in Fig. 3.

Fig. 5 is the same intraluminal device as in Fig. 3 illustrating only the outer surface cover.

Fig. 6 is the same intraluminal device as in Fig. 3 with the exception that only a liner or inner surface cover is shown.

Fig. 7 is a cross-section of the porous PTFE material of the present invention.

Fig. 8 is a schematic representation of ePTFE prior art.

DETAILED DESCRIPTIONS OF THE PREFERRED EMBODIMENTS

The present invention provides a covered stent which may be implanted intraluminally within a body vessel and disposed adjacent an occluded, weakened or otherwise damaged portion of the vessel so as to hold the vessel open. The covered stent is typically delivered intraluminally via a balloon catheter. The device is delivered in a compressed condition and once properly positioned may be deployed by radial expansion. The most common form of deploying the intraluminal device is by balloon expansion, however, the present invention may also be deployed by use of a self-expanding stent.

Fig. 1 illustrates an intraluminal device in the form of a stent 12. Fig. 2 illustrates an intraluminal device in the form of a stent 5 having a different construction than that shown in fig. 1.

Fig. 3 illustrates generally at 10 an intraluminal device in the form of a stent 12 as shown in fig. 1 having a cover 14 on the outer surface 12 and liner 16 on the inner surface, both of which may be of the porous structure shown below in fig. 7. The stent may optionally have only a cover 14 as shown in fig. 5, or only a liner 16 as shown in fig. 6, or both as shown in fig. 3. In a preferred embodiment, the stent has both a cover 14 and a liner 16. The liner, cover, or both, will be referred to hereinafter collectively as a cover or covering. The cover provides an

effective barrier about the stent 12 preventing excessive cell or tissue ingrowth or thrombus formation through the expanded wall of the stent 12.

Fig. 4 is a cross-sectional view of the same device as shown in fig. 3 with a cover 14 and a liner 16 around stent 12.

Fig. 1 is a more detailed illustration of stent 10 and shows generally an elongate tube. The body of stent 12 defines an opposed interior surface 11 and an exterior surface 13 and is formed of a generally open configuration having a plurality of openings or passages provided for longitudinal flexibility of the stent as well as permitting the stent to be radially expanded once deployed in the body lumen. Both the interior surface 11 and the exterior surface 13 may have the porous PTFE covering of the present invention. On the interior surface the covering is referred to as the liner 12 as shown in Fig. 1 and on the exterior surface it is referred to as a cover 14 as shown in Fig. 1.

While the figures illustrate a particular construction of stent 10, one of skill in the art would recognize that the porous PTFE covering material as described by the present invention would find utility in any stent configuration, and in particular the open stent configurations.

Stent 12 may be employed in combination with a cover 14 or liner 16 but is preferably employed with both. The cover 14 may be applied over the tubular stent 12 so as to fully circumferentially surround the stent 12, while the liner 16 is applied inside and through the stent 12 so that the stent 12 fully circumferentially surrounds the liner 16.

The porous polytetrafluoroethylene (PTFE) material useful herein is first obtained in the form of an interpenetrating network of PTFE and siloxane, in particular, polydimethylsiloxane. The silicone is then extracted from the IPN using either thermal or chemical means. The removal of the silicone leaves behind a porous PTFE structure. A particular material for use herein is Silon®, an interpenetrating polymer network (IPN) of polytetrafluoroethylene (PTFE) and polydimethylsiloxane (silicone) supplied by Bio Med Sciences, Inc. located in Bethlehem,

PA. Such IPN polymer networks are described in US 6022902 incorporated by reference herein in its entirety. In this patent, Silon® is described as a breathable, hydrophobic polysiloxane membrane reinforced with poly(tetrafluoroethylene).

The removal of the siloxane from the IPN leaves behind a porous PTFE structure without having to go through the added steps of stretching or expanding the PTFE in order to obtain the porous structure. Quite obviously, this simplifies the manufacturing process by decreasing the number of steps required, and also increases efficiency. Typically, porous PTFE requires the expanding and stretching steps in order to achieve the porous structure. Fig. 7 illustrates generally at 20 a porous PTFE structure after removal of the siloxane. The removal of the siloxane leaves behind the porous structure wherein voids or pockets of air 25, are found intermeshed in between pockets of PTFE 30.

The novel porous PTFE structure produced by the present inventive process is quite different from the porous structure produced by PTFE which has been stretched, or expanded. Typically, PTFE which has been stretched, or ePTFE has a node and fibril structure as seen in Figure 8. After stretching, the ePTFE possesses nodes 32 connected to fibrils 34. In between the nodes and fibrils are pores 36.

Removing the siloxane from the IPN of siloxane/PTFE through the use of heat involves heating the IPN structure to temperatures of between about 300°C and about 390°C. Chemical removal of the siloxane may be accomplished using a compound selected from the group consisting of toluene, heptane, chloroform.

Sintering is typically accomplished at or above the crystalline melting point of PTFE. Sintering is synonymous with recrystallization. It refers to the bonding of particles in a mass by molecular (or atomic) attraction in the solid state through the application of heat below the melting point of the polymer. Sintering causes the strengthening of the powder mass and normally results in densification and often recrystallization.

A PTFE tube may be extruded as a tube from an extrusion device, or extruded as a film and subsequently wrapped into a tube. Extrusion techniques of PTFE are well known in the art.

As discussed above, the stent may be covered on the interior surface 11 of the stent 10, the exterior surface 13 of the stent 10, or both. Preferably, the stent 10 is covered on both the interior 11 and the exterior 13 surfaces of the stent 10. Having the entire surface of the stent 10 covered with the porous PTFE of the present invention provides an effective barrier about the stent 10 preventing excessive cell or tissue growth, or thrombus formation through the expanded wall of a tubular stent 10.

In order for the covering of porous PTFE to function effectively in combination with an expandable stent, the material must exhibit sufficient expansion characteristics so as to enable the stent cover to expand along with the radial expansion of the stent 10. If the covering material does not effectively expand with the stent, several problems can arise. The covering material may tear, and may even detach from the surface of the stent if improper or dissimilar expansion of the covering material occurs with the expansion of the stent.

In order to improve the adhesion, and further prevent detachment of the PTFE covering from the stent, the PTFE may be fused or welded around or to the metal stent. This may be accomplished either through a heating process and/or bonding process. If heating is utilized, typically the PTFE will be heated above its sintering temperature.

If an adhesive is utilized, preferably a biocompatible adhesive is used. Such adhesives are known to one of skill in the art and include, for example, polyurethanes, epoxies, cyanoacrylates, polyamides, polyimides, silicones, and so forth. Dispersions of PTFE or FEP (fluoroethylpropylene) may also be utilized. This list is not exclusive and is intended for illustrative purposes only, and is in no way intended as a limitation on the scope of the present invention. There is a vast number of adhesives that can be used for such applications, limited by their biocompatibility, and by their ability to bond to polymeric materials (e.g. PTFE) and metals, particularly in aqueous environments.

The covering material may also be assembled to the intraluminal device in more than one piece. Such a combination would require overlapping of sorts of the PTFE material, and subsequent fusion or adhesive bonding of the porous PTFE material to itself.

It is preferable, however, to utilize the porous PTFE covering in a continuous form such as a membrane or thin film. The porous PTFE (after removal of the siloxane), in the form of a membrane or a thin film, thus, preferably completely wraps the metal stent, thereby providing a barrier that physically isolates the stent from surrounding blood and tissue. This barrier further helps prevent healing or diseased layers of tissue from directly contacting the stent, or from passing through the stent in any way. The porous PTFE allows the passage of fluids and vital materials, however, while still serving as a barrier to tissue growth.

CLAIMS:

1. An endoprosthesis device comprising:

an elongate radially expandable tubular stent having an interior surface and an exterior surface extending along a longitudinal stent axis; and

a stent cover on said interior surface, exterior surface or both, said stent cover being formed of a porous polytetrafluoroethylene;

wherein said porous polytetrafluoroethylene is formed by the steps of:

providing an interpenetrating network of siloxane/polytetrafluoroethylene;

removing said siloxane from said interpenetrating network leaving a porous polytetrafluoroethylene structure.

2. The endoprosthesis device of Claim 1 wherein said stent cover is on said exterior surface and said interior surface of said stent.

3. The endoprosthesis device of Claim 1 wherein said stent cover is expandable upon expansion of said stent.

4. The endoprosthesis device of Claim 1 wherein said siloxane is chemically extracted from said siloxane/polytetrafluoroethylene interpenetrating network.

5. The endoprosthesis device of Claim 4 wherein said siloxane is chemically extracted by a compound selected from the group consisting of toluene, heptane and chloroform.

6. The endoprosthesis device of Claim 1 wherein said siloxane is removed from said siloxane/polytetrafluoroethylene interpenetrating network by heating said network to a temperature of at least about 300°C.

7. A method of covering an endoprosthesis device comprising the steps of:

providing an elongate radially expandable tubular stent;

providing a porous polytetrafluoroethylene by extracting siloxane from an interpenetrating network of siloxane and polytetrafluoroethylene;

forming a stent cover from said porous polytetrafluoroethylene; and

applying said stent cover to said interior surface, said exterior surface, or both of said stent wherein said stent cover extends along the longitudinal stent axis.

8. The method of Claim 7 wherein said stent cover is applied to said interior surface and to said exterior surface of said stent.

9. The method of Claim 7 wherein said stent cover is fixed to said stent using an adhesive.

10. The method of Claim 9 wherein said adhesive is selected from the group consisting of polyurethanes, epoxies, cyanoacrylates, polyamdies, polyimides, and silicones.

11. The method of Claim 7 wherein said stent cover is fixed to said stent by a welding process, said welding process comprising heating the polytetrafluoroethylene stent cover to a temperature that is greater than the sintering temperature of the polytetrafluoroethylene.

12. A method for producing a porous polytetrafluoroethylene tube useful in medical devices comprising the steps of:

providing an interpenetrating network of siloxane and polytetrafluoroethylene; and

removing said siloxane from said interpenetrating network leaving a porous polytetrafluoroethylene structure.

13. An endoprosthesis device comprising:

an elongate radially expandable tubular stent having an interior surface and an exterior surface extending along a longitudinal stent axis; and

a stent cover on said interior surface, exterior surface or both, which is formed of a porous polytetrafluoroethylene;

wherein said porous polytetrafluoroethylene comprises a non-stretched porous structure.

14. An endoprosthesis device according to claim 13 wherein said polytetrafluoroethylene lacks node and fibril structure.

15. The endoprosthesis device of claim 13 wherein said stent cover is on said exterior surface and said interior surface of said stent.

16. The endoprosthesis device of claim 13 wherein said stent cover is expandable upon expansion of said stent.

STENT COVERING FORMED OF POROUS POLYTETRAFLUOROETHYLENE

ABSTRACT

An endoprosthesis device and method of making it are disclosed. More particularly, the endoprosthesis is a porous PTFE article used in conjunction with a stent.

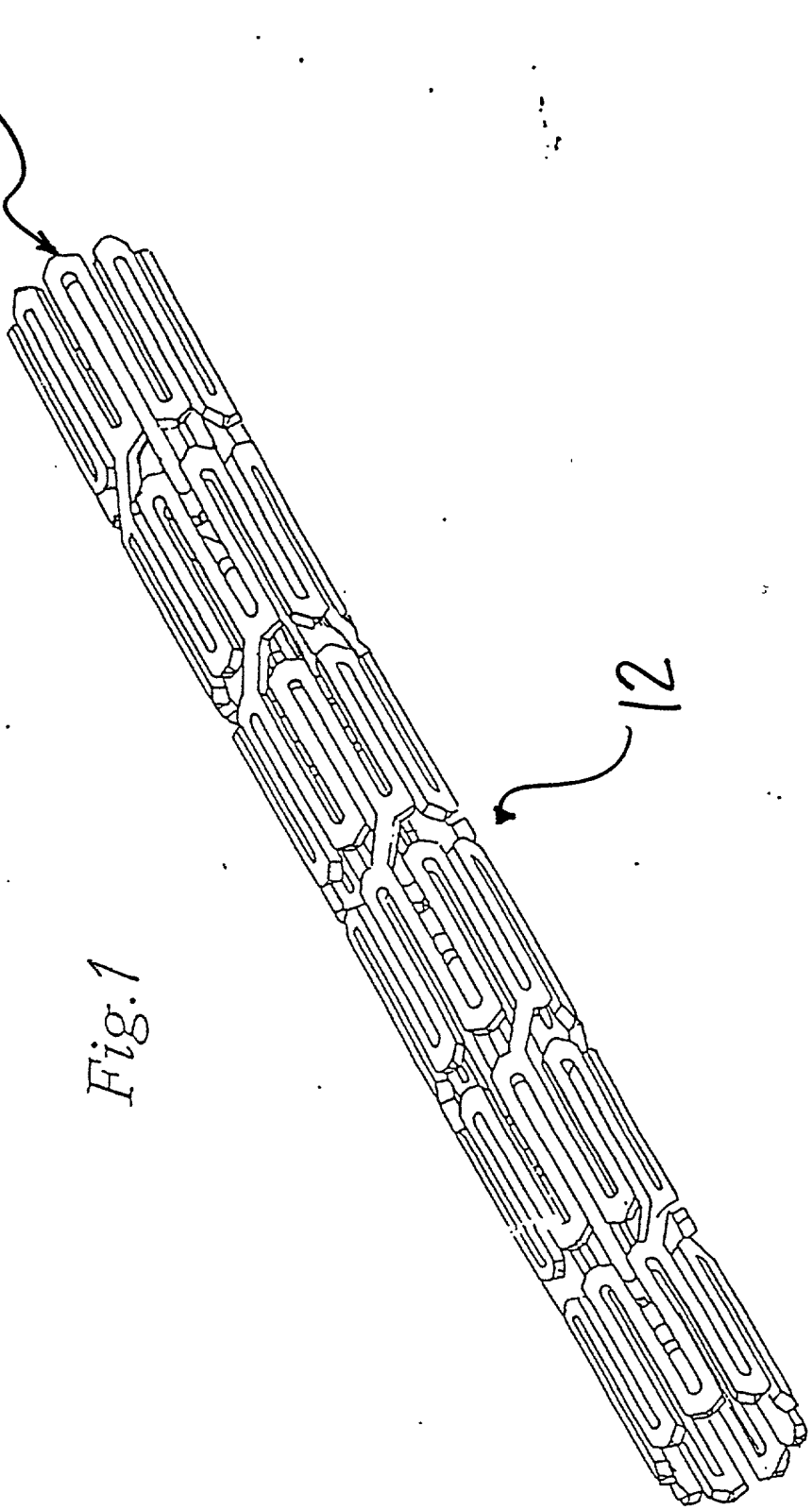


Fig. 1

Fig. 2

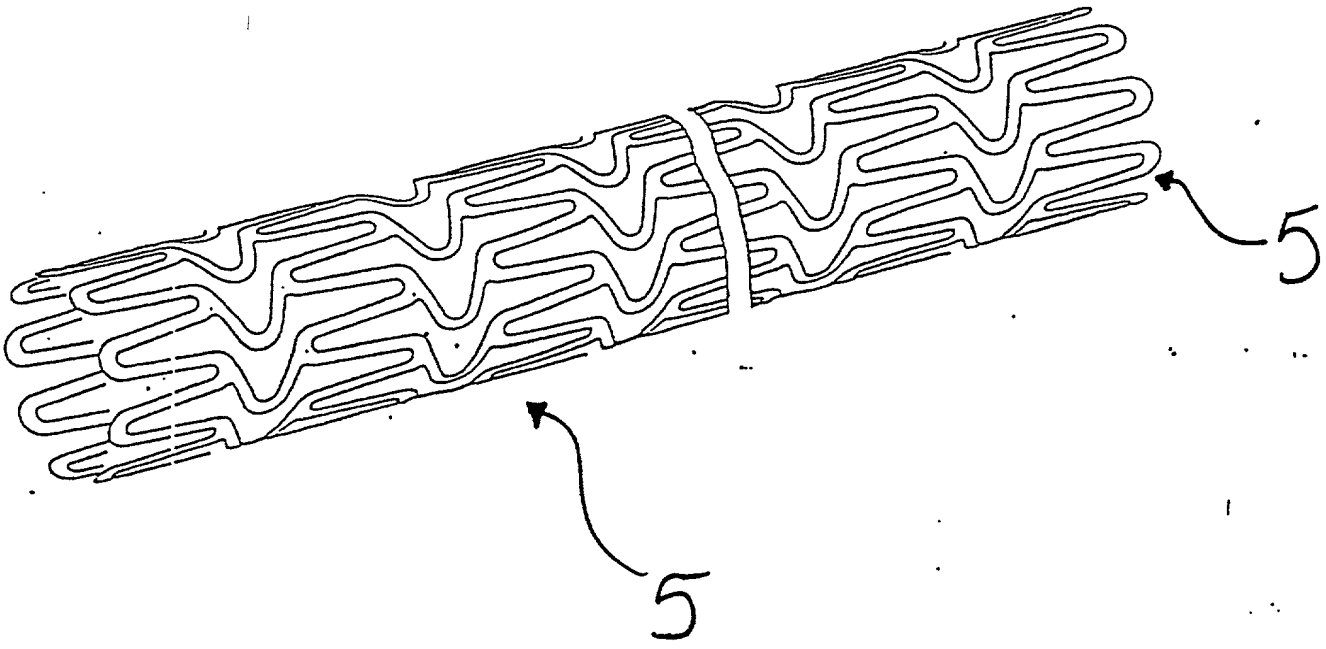


FIG.3

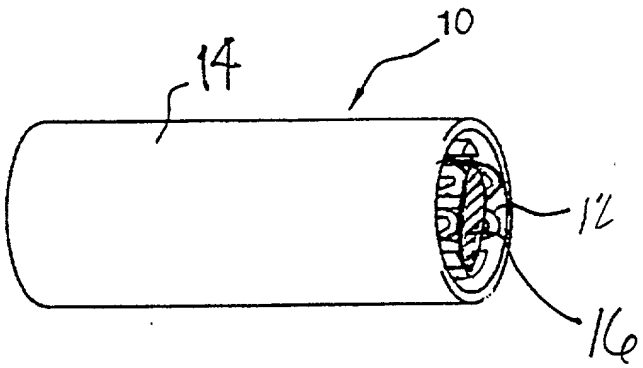


Fig. 4

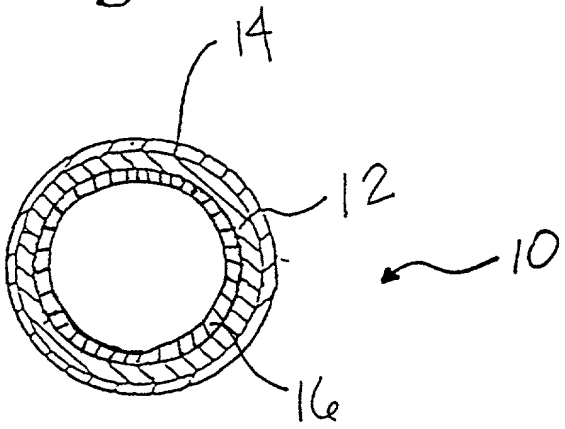


FIG. 5

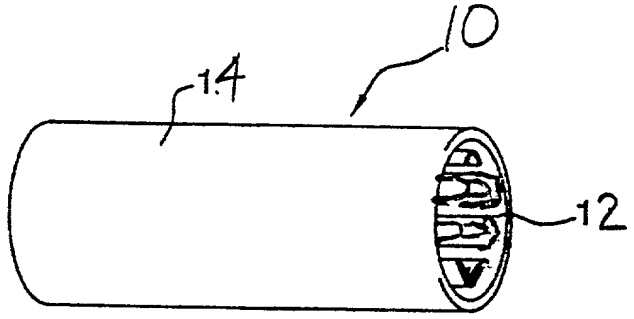


Fig. 6

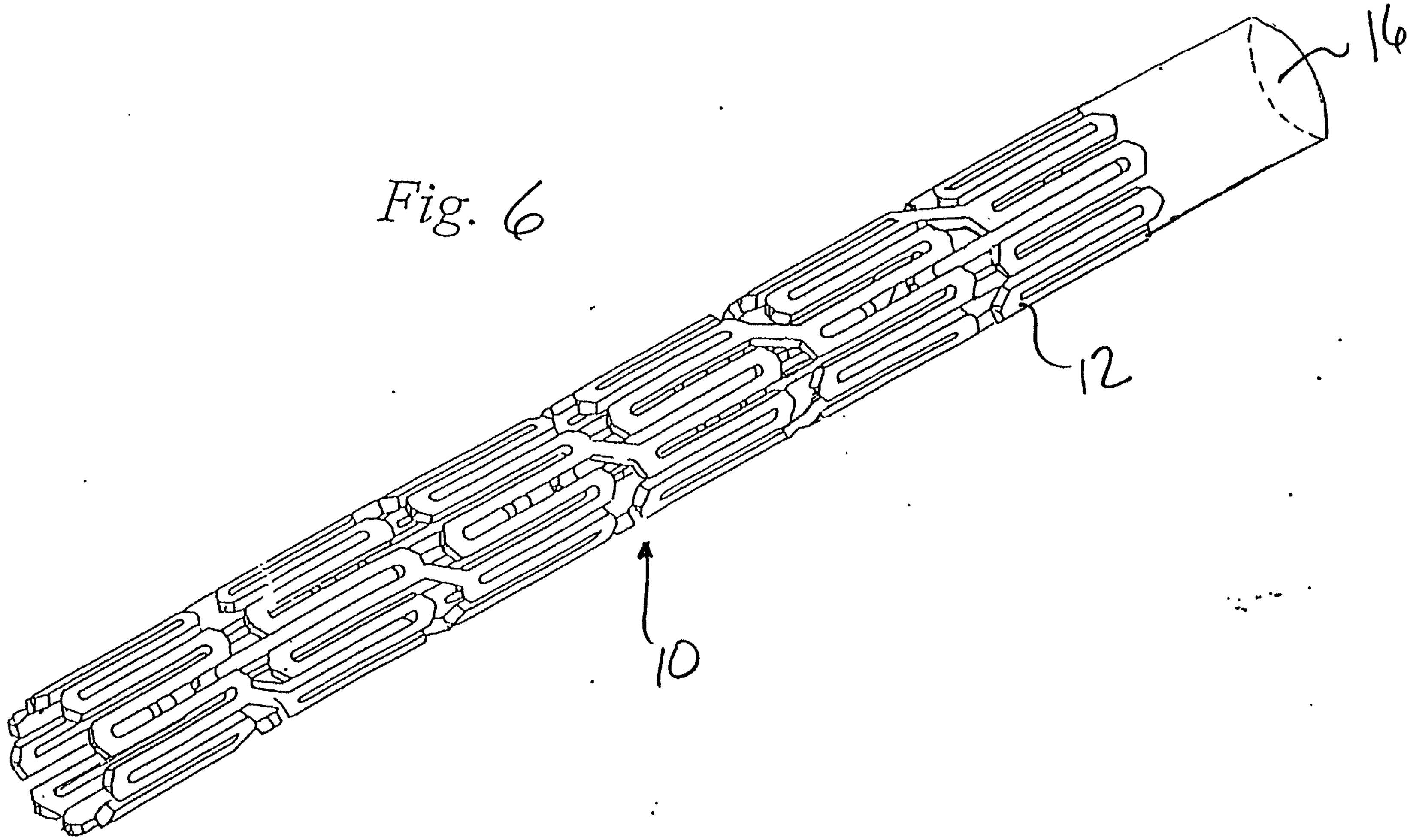


FIG. 7

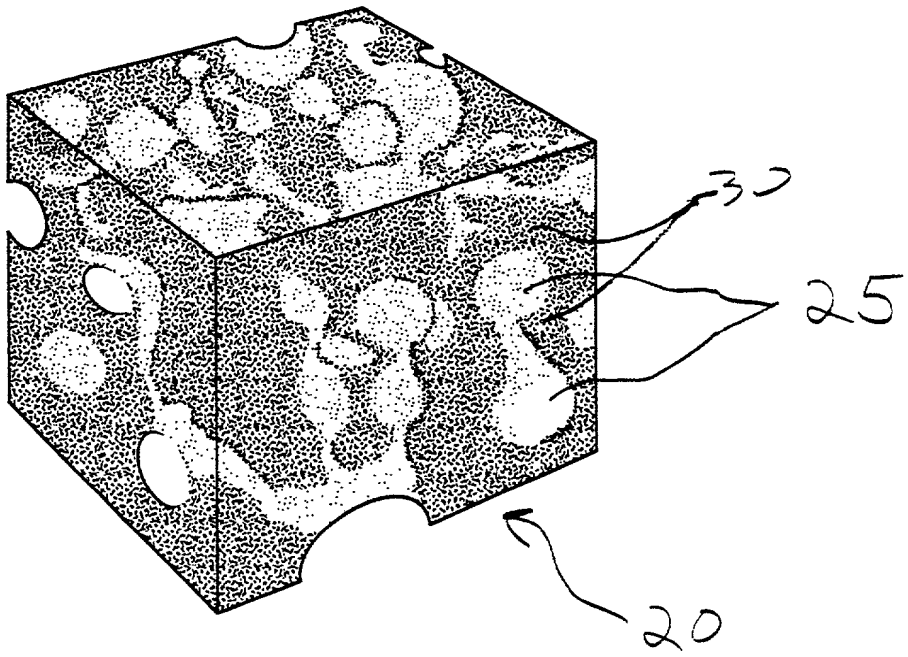
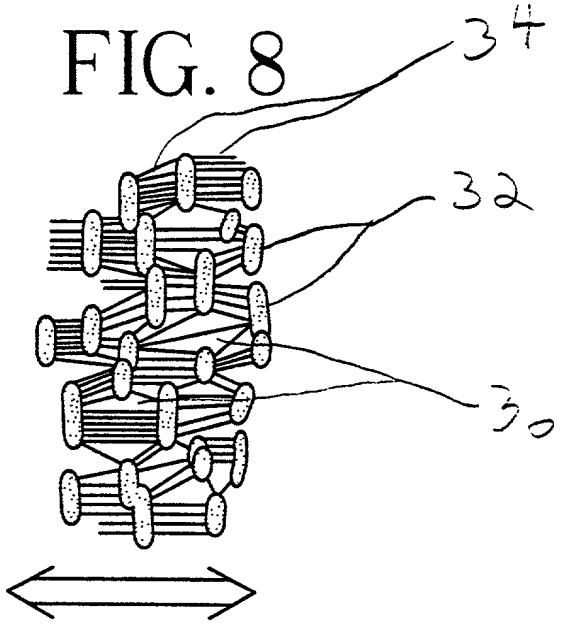


FIG. 8



PATENT

Attorney's Docket No. **760-35**

COMBINED DECLARATION AND POWER OF ATTORNEY

(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL, CONTINUATION OR CIP)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type: *(check one)*

- ☒ Original
- ☐ Supplemental
- ☐ Design
- ☐ National Stage PCT
- ☐ Divisional
- ☐ Continuation
- ☐ Continuation-in-Part (CIP)

INVENTORSHIP IDENTIFICATION

NOTE: If the inventors are each not the inventors of all the claims an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

STENT COVERING FORMED OF POROUS POLYTETRAFLUOROETHYLENE

the specification of which: *(complete (a), (b) or (c))*

(a) ☒ is attached hereto.

(b) ☐ was filed on _____ as
☐ Serial No. 60/_____ or
☐ Express Mail No. _____, as Serial No. not yet known
and was amended on _____. *(If applicable)*

(c) ☐ was described and claimed in PCT International Application No. **PCT/** _____
filed on _____ and as amended under PCT Article 19 on _____. *(If any)*

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above, and that the filing of said specification, if heretofore filed, was authorized by me.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

CLAIM OF PRIORITY OF EARLIER FOREIGN APPLICATION(S) UNDER 35 U.S.C. §119(a)-(d)

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

(List prior foreign/PCT application(s) filed within 12 months (6 months for design) prior to this U.S. application.)

NOTE: Where item (c) is entered above and the International Application which designated the U.S. claimed priority check item (e), enter the details below and make the priority claim.

COUNTRY (orPCT)	APPLICATION NO.	DATE OF FILING *(Day/Month/Year)*	PRIORITY CLAIMED UNDER 35 USC §119
			☐ YES ☐ NO
			☐ YES ☐ NO

CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S) UNDER 35 U.S.C. §119(e)

I hereby claim the benefit under Title 35, United States Code, §119(e) of any United States provisional application(s) listed below:

(List prior U.S. provisional applications.)

PROVISIONAL APPLICATION NO.	FILING DATE *(Day/Month/Year)*

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S) UNDER 35 U.S.C. 120

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in such prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

(List prior U.S. applications or PCT international applications designating the U.S. for benefit under 35 U.S.C. §120.)

U.S. APPLICATIONS		**STATUS** *(Check One)*		
U.S. SERIAL NO.	U.S. FILING DATE *(Day/Month/Year)*	Patented	Pending	Abandoned
0 /		☐	☐	☐
0 /		☐	☐	☐

PCT APPLICATIONS DESIGNATING THE U.S.			**STATUS** *(Check One)*		
PCT APPLN. NO.	PCT FILING DATE *(Day/Month/Year)*	U.S. SERIAL NOS ASSIGNED (If any)	Patented	Pending	Abandoned
PCT/			☐	☐	☐
PCT/			☐	☐	☐

35 USC 119 PRIORITY CLAIM, IF ANY, FOR ABOVE LISTED U.S./PCT APPLICATIONS

PRIORITY APPLICATION NO.	PRIORITY COUNTRY	FILING DATE *(Day/Month/Year)*	ISSUE DATE *(Day/Month/Year)*

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office in connection therewith:

Charles R. Hoffmann, Reg. No. 24,102; Ronald J. Baron, Reg. No. 29,281; Gerald T. Bodner, Reg. No. 30,449; Alan M. Sack, Reg. No. 31,874; A. Thomas Kammer, Reg. No. 28,226; R. Glenn Schroeder, Reg. No. 34,720; Glenn T. Henneberger, Reg. No. 36,074; Irving N. Feit, Reg. No. 28,601; Anthony E. Bennett, Reg. No. 40,910; Gregory W. Bachmann, Reg. No. 41,593; Steven T. Zuschlag, Reg. No. 43,309; Susan A. Sipos, Reg. No. 43,128, Kevin E. McDermott, Reg. No. 35,946; Robert C. Morriss, Reg. No. 42,910; Roderick S.W. Turner, Reg. No. 38,639; James F. Harrington, Reg. No. 44,741; Richard LaCava, Reg. No. 41,135; Algis Anilionis, Reg. No. 36,995; Justin K. Holmes, Reg. No. 42,666; and Robert L. Bernstein, Reg. No. P-46,020, each of them of HOFFMANN & BARON, LLP, 6900 Jericho Turnpike, Syosset, New York 11791; and Daniel A. Scola, Jr., Reg. No. 29,855; Salvatore J. Abbruzzese, Reg. No. 30,152; Kellyanne Merkel, Reg. No. 43,800; John Sopko, Reg. No. 41,321; Barry Jacobsen, Reg. No. 43,689; Gloria K. Szakiel, Reg. No. 45,149; Mark E. Baron, Reg. No. 46,150; and Clinton J. Cusick, Reg. No. 43,573, each of them of HOFFMANN & BARON, LLP, 1055 Parsippany Boulevard, Parsippany, New Jersey 07054; and Mark J. Casey, Reg. No. 37,796; David L. Cavanaugh, Reg. No. 36,476; Luke R. Dohmen, Reg. No. 36,783; Peter J. Gafner, Reg. No. 36,517; Patricia LaMarche-Davis, Reg. No. 37,866; Robert M. Rauker, Reg. No. 40,782; Scott T. Bluni, Reg. No. 40,916, each of them of Boston Scientific Corporation, One Boston Scientific Place, Natick, MA 01760-1537.

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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Full Name of Sole or First Inventor:	Timothy Samuel Girton
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Date: 10/30/00	Inventor's signature Timothy Girton

NOTE: All above spaces identifying inventors must be completed or deleted before any inventor executes this application